

Remarks

Claims 25-46 are pending in the instant application. Claims 25-46 have been rejected by the Examiner.

By the above amendments, Claims 36, 37 and 45 have been canceled without prejudice, and Claim 25 amended to more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More particularly, Claim 25 has been amended to limit the low solubility therapeutic agent to topiramate, and to require that the release of the therapeutic agent to the environment occurs as a solution or suspension. Support for the amendments to Claim 25 may be found in paragraphs [00067] and [00073] of the specification as originally filed. Applicants submit that the amendments are fully supported by the specification as filed, and no new matter is being added. Applicants also submit that the amendments limiting the therapeutic agent to topiramate and canceling Claims 36, 37 and 45 are being made solely to advance the prosecution of the instant application and are not in any way to be construed as an admission that the canceled material is unpatentable. Thus, Applicants reserve the right to pursue coverage of the canceled material by filing a continuation or a divisional application at an appropriate time in the future. After entry of the amendments, Claims 25-35, 38-44 and 46 will remain pending and under consideration. Reconsideration of the captioned application based on the previous amendments and following remarks is respectfully requested.

The Examiner has rejected Claims 25-31, 41 and 42 under 35 U.S.C. §102(b) as being anticipated by Bhatt, *et al.* (U.S. Patent No. 6,368,626).

By the above amendments, Applicants have amended independent Claim 25 to limit the low solubility therapeutic agent to topiramate. Since Bhatt *et al.* do not disclose topiramate as the active ingredient in the controlled release dosage forms of Bhatt *et. al.*, Applicants submit that the reference does not anticipate the instant invention, and Applicants respectfully request that the Examiner withdraw the rejection of Claims 25-31, 41 and 42 under §102(b).

The Examiner has rejected Claims 45 and 46 under 35 U.S.C. §103(a) as being unpatentable over Bhatt, *et al.* (U.S. Patent No. 6,368,626) in view of Chen, *et al.* (U.S. 2003/0077297). The Examiner states:

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add topiramate and poloxamer 407 to a controlled release formulation, as taught by Bhatt, *et. al.* in view of Chen, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to make a dosage form comprising a core (consisting of a low solubility therapeutic agent, a structural polymer, and a solubilizing surfactant) surrounded by a semi-permeable membrane, and an exit orifice because of the beneficial effects substantially complete release of a drug from the dosage form, particularly dosage forms that may require high drug loading in order to have the desired pharmacological effect, as explained by Bhatt, *et. al.*

Applicants respectfully traverse this rejection.

By the above amendments, Applicants have canceled Claim 45 and amended independent claim 25 to require that the release of the therapeutic agent (topiramate) to the environment occurs as a solution or suspension. By contrast, the dosage form taught by Bhatt, *et. al.* is designed to release the active ingredient from the dosage form in "a dry or substantially dry state". (see, e.g., column 5, lines 34-41 and Claim 1 of Bhatt, *et al.*) Bhatt, *et.*

al. defines "dry state" or "substantially dry state" to mean that "the composition forming the drug layer of the dosage form is expelled from the dosage form in a plug-like state, the composition being sufficiently dry or so highly viscous that it does not readily flow as a liquid stream from the dosage form under the pressure exerted by the push layer." (see, column 5, lines 28-33 of *Bhatt, et. al.*) Applicants submit that the combined teachings of *Bhatt, et. al.*, which teach release of the drug layer from the dosage form in a "dry or substantially dry state", and *Chen, et. al.*, which teach topiramate and poloxamer 407, would not motivate one of ordinary skill in the art to make the claimed dosage form which releases the drug layer from the dosage form as a solution or suspension. Thus, Applicants urge that the combined teachings of *Bhatt, et. al.* and *Chen, et. al.* do not render the present invention obvious, and Applicants respectfully request that the Examiner withdraw the rejection of Claims 45 and 46 under 35 U.S.C. §103(a).

The Examiner has rejected Claims 32-40, 43 and 44 under 35 U.S.C. §103(a) as being unpatentable over *Bhatt, et al.* (U.S. Patent No. 6,368,626). The Examiner states:

Bhatt, et. al. disclose a controlled release oral dosage form (see above).

While *Bhatt, et. al.* do not explicitly teach all the instant claimed percentages and dosage levels, it would have been obvious to a one of ordinary skill in the art at the time the invention was made to determine suitable percentages and dosages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in percentage and dosage level will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such percentage and dosage level is critical. . . . Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage and dosage level ranges.

Applicants respectfully traverse this rejection.

As described in detail above, the dosage form taught by Bhatt, *et. al.* is designed to release the active ingredient from the dosage form in "a dry or substantially dry state" (see, e.g., column 5, lines 34-41 and Claim 1 of Bhatt, *et al.*), which is defined to mean that "the composition forming the drug layer of the dosage form is expelled from the dosage form in a plug-like state, the composition being sufficiently dry or so highly viscous that it does not readily flow as a liquid stream from the dosage form under the pressure exerted by the push layer." (see, column 5, lines 28-33 of Bhatt, *et. al.*) By the above amendments, Applicants have limited the claims to require that the release of the therapeutic agent (topiramate) to the environment occurs as a solution or suspension. Applicants submit that the teaching of Bhatt, *et. al.*, which teach release of the drug layer from the dosage form in a "dry or substantially dry state", would not motivate one of ordinary skill in the art to make the claimed dosage form which releases the drug layer from the dosage form as a solution or suspension. Thus, Applicants urge that the teaching of Bhatt, *et. al.* does not render the present invention obvious, and Applicants respectfully request that the Examiner withdraw the rejection of Claims 32-40, 43 and 44 under 35 U.S.C. §103(a).

The Examiner has provisionally rejected Claims 25-44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-41 of co-pending Application No. 10/404,166 ('166). Applicants respectfully traverse this rejection.

Applicants urge that the claims of the '166 application do not render the present invention obvious. In considering whether the instant claims define merely an obvious variation of the invention disclosed and claimed in the '161 application, the patent disclosure (other than that portion of the disclosure defining the claims in the '161 application) cannot be used as prior art. Thus, there must be some other teaching in the art to modify the dosage forms as claimed in the '161 application to those of the present invention. Applicants submit that the claims of the '161 application are directed to a controlled release dosage form comprising an osmotic core containing an active agent and expandable push layer, a bi-layer membrane system (an osmoresponsive membrane and a semipermeable membrane) positioned around at least part of the osmotic core and a delivery passageway. The claims of the '161 application provides absolutely no teaching as to the composition of the osmotic core of the dosage form, while the instantly claimed invention requires a dosage form comprising a core which comprises a low solubility therapeutic agent (topiramate); a structural polymer; and a solubilizing surfactant. Moreover, the claims of the '161 application provide no teaching or suggestion that the dosage form should release the therapeutic agent from the dosage form as a solution or suspension, as is required by the claims of the instant application. Since the claims of the '161 application would not motivate one of ordinary skill in the art to make the claimed invention, Applicants submit that the Examiner has failed to establish a *prima facie* case of obviousness. Thus, Applicants respectfully request that the Examiner withdraw the obviousness-type double patenting rejection.

In view of the above amendments and remarks, Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

Respectfully submitted,

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